# **Proposal Summary/Overview**

To be completed by proposal sponsor. (500 Word Count Limit for this page) Please read the entire questionnaire before completing this page.

Name: Sarah Derr, Pharm D MPhA ED

Organization: Minnesota Pharmacy Alliance (MPA): Minnesota Pharmacists Association (MPhA), Minnesota Society of

Health-System Pharmacists (MSHP), University of Minnesota College of Pharmacy (UMN CoP) **Phone:** Please contact Buck Humphrey, MPA's Gov Affair rep, with any questions: 612-889-6515

Email Address: hubert4@gmail.com; sarahd@mpha.org

*Is this proposal regarding:* 

- New or increased regulation of an existing profession/occupation? If so, complete Questionnaire A.
- Increased scope of practice or decreased regulation of an existing profession? If so, complete this form,
   Questionnaire B.
- Any other change to regulation or scope of practice? If so, please contact the Committee Administrator to discuss how to proceed.
- 1) State the profession/occupation that is the subject of the proposal.

Pharmacist, pharmacy intern, pharmacy technician

#### 2) Briefly describe the proposed change.

Since being authorized in 2020 Minnesota pharmacists and pharmacy technicians have provided over 4 million vaccinations and boosters and at least 37% (<u>Doses Administered</u>, <u>by Provider</u>) of the millions of COVID-19 vaccinations, flu vaccines and other approved FDA vaccines through injection to patients across the state. Minnesota pharmacists provided hundreds of mental health and substance abuse medication injections a week to patients across Minnesota in 2021 & 2022. In particular, rural pharmacies are working with providers to help patients with their mental health injectable medication needs.

In 2020 the federal government fortunately recognized the vastness of the problem the pandemic would bring and the logistical challenges that would accompany inoculating an entire population while continuing to provide for the treatment and care for patients in ICUs, clinics, long term care and in other settings as well as ongoing general population health needs. They also were seeing consequences such as immunizations falling at an alarming rate. These immunization trends have not reversed back to pre-pandemic levels.

Unless the Minnesota legislature enacts these modest scope changes for pharmacists, pharmacist interns and pharmacy technicians in Minnesota statute, Minnesota pharmacies will be turning away patients across the state when they come with family members to get vaccinated and/or tested at Minnesota pharmacies for a variety of immunizations and many CLIA waived tests that they have come accustomed to receiving care at their community pharmacy. In order to inoculate/vaccinate the vast majority of Americans, they would need all trained health professionals in the fight. Fortunately, there was a highly qualified resource, pharmacists, interns and pharmacy techs, that could make an enormous impact, right away, safely and trusted in all geographic locations in the country.

Minnesota is a great example of urban, rural and suburban pharmacy stepping into the breach and taking care of Minnesotans. MN pharmacy has administered over 4 million COVID-19 vaccines as well as boosters and many of

those were administered to children 5 years of age and older (<a href="https://mn.gov/covid19/vaccine/data/index.jsp">https://mn.gov/covid19/vaccine/data/index.jsp</a>) This does not include doses that have been set aside for the CDC's Pharmacy Partnership Program for vaccination in long-term care settings .

Now, with the announcement that the Biden Administration will not be renewing the Presidential Health Emergency – emergency authorities for the health emergency including those authorities granted to pharmacists, pharmacist interns and pharmacy technicians across Minnesota. If these authorities are not codified in Minnesota statute by May 11, 2023, pharmacist interns and pharmacy technicians will no longer be allowed to administer vaccines along with other test ordering authorities granted from the emergency declarations.

The federal PREP Act has enabled pharmacists, pharmacy technicians, and pharmacy interns to administer indicated immunizations to patients 3 years of age and older. It has also ensured that patients are able to receive COVID-19 and other non-lab (FDA approved-CLIA waived) tests in a timely fashion. Currently under Minnesota law, pharmacists are allowed to administer COVID-19 and Flu vaccinations to all patients 6 years and older and inoculate Minnesotans 13 years and older for all other FDA approved vaccines. In order for the state not to go backwards, this bill would make permanent in MN state law pharmacists, pharmacist interns and pharmacy technicians' ability to inoculate Minnesotans 3 years of age and older. In addition, pharmacists would be able to order and pharmacy technicians would be allowed to administer CLIA-waived tests (e.g. A1c, influenza, etc.) under the supervision of a pharmacist. Pharmacists would maintain their current Minnesota statutory authorities to interpret CLIA waived test results and make modifications to medication therapies under a Collaborative Practice Agreement (CPA).

The proposed modifications to the MN pharmacy practice act (<u>Chapter 151</u>) would provide authority for pharmacists, pharmacist technicians and interns in Minnesota to offer vaccinations and point-of-care testing to individuals in Minnesota that they are currently providing health services and care for. The proposed legislation would put in place, codify their authority to provide these same services for patients after May 11<sup>th</sup>, 2023, when most of the federal emergency pandemic authorities are no longer in effect.

Included is a study recently published by IQVIA (Attached) which looks at the impact pharmacy across the country has made for access to immunizations at all age levels. This is all during a time when the past month, the StarTribune has run reported several times about the decrease in immunizations both here in Minnesota and around the country (see below). Also included is the 2020 HHS PREP Act guidelines which our legislation incorporates.

Tuesday, January 31st, 2023 - The Hill: Getting vaccinated at pharmacies works: It could soon disappear <a href="https://thehill.com/opinion/healthcare/3835860-getting-vaccinated-at-pharmacies-works-it-could-soon-disappear/">https://thehill.com/opinion/healthcare/3835860-getting-vaccinated-at-pharmacies-works-it-could-soon-disappear/</a>

# StarTribune 1/12/23:

Pediatric vaccinations decline in Minnesota amid COVID-19, parent hesitancy <a href="https://www.startribune.com/pediatric-vaccinations-decline-in-minnesota-amid-covid-19-parent-hesitancy/600242984/">https://www.startribune.com/pediatric-vaccinations-decline-in-minnesota-amid-covid-19-parent-hesitancy/600242984/</a>

# StarTribune 1/13/23:

Minnesota snuffed measles clusters in 2022, but risks remain <a href="https://www.startribune.com/minnesota-snuffed-measles-clusters-in-2022-but-risks-remain/600243326/">https://www.startribune.com/minnesota-snuffed-measles-clusters-in-2022-but-risks-remain/600243326/</a>

### Reuters - 1/12/23:

U.S. childhood vaccinations dip again in 2021-'22 school year -study <a href="https://www.reuters.com/world/us/us-childhood-vaccinations-dip-again-2021-22-school-year-study-2023-01-12/">https://www.reuters.com/world/us/us-childhood-vaccinations-dip-again-2021-22-school-year-study-2023-01-12/</a>

3) If the scope of practice of the profession/occupation has previously been changed, when was the most recent

change? Describe the change and provide the bill number if available.

The scope of pharmacy in Minnesota and across the US was expanded to include broader immunizations and testing at pharmacies by the President declaring a Health Emergency and implementing authorities the federal government has from the federal PREP Act emergency health declarations. Minnesota's current pharmacy immunizations and testing laws have been in place for more than a decade. More recently, pharmacists were given the authority to give Sub Q and IM prescribed injections, were authorized to prescribe hormonal contraceptives, work with patients that are trying to quit smoking tobacco through a smoking replacement patient program and pharmacists are able to prescribe Narcan for resuscitating a person who has overdosed from heroin or opioids.

- 4) If the proposal has been introduced, provide the bill number and names of House and Senate sponsors. If the proposal has not been introduced, indicate whether legislative sponsors have been identified. If the bill has been proposed in previous sessions, please list previous bill numbers and years of introduction.
  - This proposed pharmacy immunization & point-of-care testing legislation HF1197 has been introduced by Representative Bahner & SF1176 has been introduced by Senator Hoffman.
  - Representatives Bahner, Ryer, Lee, Bierman, Fischer, Hussein, Elkins, Finke, Carroll, Hemmingsen-Jaeger, Her & Smith have all co-authored the legislation in the Minnesota House.
  - Senators Hoffman, Bolden and Duckworth are authors of the Senate legislation. Last session the same legislation
    was introduced and supported by Rep.s Bahner, Huot, Baker, Hamilton, Davids, and other House members
    expressed interest and support for this legislation. Senators Duckworth, Klein and Abeler also expressed their
    support for the changes to the pharmacy practice act.
  - This bill was introduced last session, HF4009 and SF3940.
- 5) Given the press of business in the 2023 legislative session it is unlikely that health licensing and scope of practice bills will be taken up this year. If there is an urgent need for the bill to be heard this year, please explain the urgency.

The proposed modifications to the MN pharmacy practice act (<u>Chapter 151</u>) would provide authority for pharmacists, pharmacist technicians and interns in Minnesota to offer vaccinations and point-of-care testing to individuals in Minnesota that they are currently providing health services and care for. The proposed legislation would put in place, codify their authority to provide these same services for patients after May 11<sup>th</sup>, 2023, when the federal PREP act emergency pandemic declarations are no longer in effect. If these changes are not made to the scope of pharmacy in Minnesota statute by May 10th, 2023 the pharmacy workforce, many pharmacy operations and patient access in Minnesota to immunizations administered at a pharmacy and by a pharmacist, pharmacist intern or pharmacy technician will be severely impacted.

Questionnaire B: Change in scope of practice or reduced regulation of a health-related profession (adapted from Mn Stat 214.002 subd 2 and MDH Scope of Practice Tools)

This questionnaire is intended to help legislative committees decide which proposals for change in scope of practice or reduced regulation of health professions should receive a hearing and advance through the legislative process. It is also intended to alert the public to these proposals and to narrow the issues for hearing.

This form must be completed by the sponsor of the legislative proposal. The completed form will be posted on the committee's public web page. At any time before the bill is heard in committee, opponents may respond in writing with concerns, questions, or opposition to the information stated and these documents will also be posted. The Chair may request that the sponsor respond in writing to any concerns raised before a hearing will be scheduled.

A response is not required for questions that do not pertain to the profession/occupation (indicate "not applicable"). Please be concise. Refer to supporting evidence and provide citation to the source of the information where appropriate.

While it is often impossible to reach complete agreement with all interested parties, sponsors are advised to try

to understand and to address the concerns of any opponents before submitting the form.

#### 1) Who does the proposal impact?

a. Define the occupations, practices, or practitioners who are the subject of this proposal.

Pharmacists, pharmacist interns, and pharmacy technicians, as well as the practice of pharmacy, are directly affected by the proposed legislation.

b. List any associations or other groups representing the occupation seeking regulation and the approximate number of members of each in Minnesota

Minnesota Pharmacists Association: just over half of the approximately 8,925 licensed pharmacists in MN.

Minnesota Society of Health-System Pharmacists: approximately 1,250+ of the total licensed pharmacists in MN.

University of Minnesota College of Pharmacy: 300+ students and faculty at the U of M – MPLS & Duluth campuses.

Pharmacists are a trusted healthcare provider that is accessible to most Minnesotans within 5 miles or 5- 10 minutes of their home. A majority of patients need no scheduled appointment to have their health needs met at a pharmacy in Minnesota. On average, patients visit their pharmacy about 18 to 25 times per year. There are approximately 21,535 Minnesota pharmacists, pharmacist interns, pharmacy technicians and front-of-house pharmacy workers.

c. Describe the work settings, and conditions for practitioners of the occupation, including any special geographic areas or populations frequently served.

The pharmacists and pharmacy technicians most impacted by the proposed legislation will be those who work at brick-and-mortar dispensing pharmacies such as chain pharmacies, independent pharmacies, discharge pharmacies, and other community pharmacies. The proposed legislation will also ensure that other pharmacists, such as those located in clinics and hospitals can continue to offer these services per their collaborative practice agreements.

However, as with almost all health care provider professions, Minnesota is in a very tight labor market and this includes pharmacists. Losing the ability to not have pharmacist interns and pharmacy technician's authority to vaccinate patients in Minnesota would have a devastating impact on access to critical immunizations across Minnesota. Many Minnesota pharmacies would not be able to continue to maintain the necessary staff and workforce to meet patient immunization and testing demand.

d. Describe the work duties or functions typically performed by members of this occupational group and whether they are the same or similar to those performed by any other occupational groups.

Similar to other healthcare providers, pharmacists are able to administer vaccinations and monitor for potential side effects, counsel patients about their medications, administer CLIA waived tests, and recommend over-the-counter medications. Pharmacy interns and technicians could be delegated these responsibilities under the proposal. Both are currently authorized and have been performing these patient tasks for close to 3 years under the federal PREP Act as well as other current state authorities.

Unique work duties for pharmacists include dispensing medications through point-of-sale monetary transactions and identifying potential drug-drug interactions. Pharmacy interns and technicians in Minnesota have many responsibilities, including filling prescriptions, stocking medications, ordering medications, filing

prescriptions, vaccinating adults and children when ACPE trained and much more.

Pharmacists overseeing and responsible for any actions associated with their or the pharmacy tech or interns administering of child vaccinations would comply with all child immunization requirements in Minnesota, including being obligated to inform a child's adult caregiver/parent at the immunization visit of the importance of receiving their "well-child" visit with a pediatrician and required communication as well as reporting immunizations of children to the Minnesota Department of Health's Minnesota Immunization Information Connection (MIIC) (https://www.health.state.mn.us/people/immunize/miic/index.html).

#### e. Discuss the fiscal impact.

There is potential savings to both the patient and the healthcare system as a whole. Patients can have access to vaccinations and CLIA-waived tests without the time and costs often required for clinic visits as well as the fee for the visit and/or the 2-6% mark up of medications acquired at the provider's office, hospital or clinic. Potential savings to the healthcare system present due to the potential for improved access to these preventative measures, potentially increasing vaccination rates and decreasing future primary care visits or hospitalizations. Greater access to vaccinations should reduce the need for disease treatments, hospitalization and other health associated costs that could occur from infection of many preventable diseases. Increased access to CLIA-waived tests can reduce time to therapy initiation and improve outcomes for therapies that are time-dependent. They also can give a patient access to convenient, relatively fast and accredited testing that can often give patients piece of mind or get them to a provider for further therapies and care.

This said, last year's fiscal note did state that the Minnesota Department of Human Services would have \$26,000 per year in additional FTE costs to register pharmacists as opposed to pharmacies See the below fiscal note assumptions. MPhA would argue that these "registration" costs should be a part of the current DHS budget.

#### 2022 Senate fiscal note Assumptions:

This bill is effective January 1, 2023. In 2020, the Department of Human Services (DHS) began reimbursing pharmacists for vaccines ordered by a pharmacist in compliance with the federal Public Readiness and Emergency Preparedness (PREP) Act, removing the requirement that prescription for the vaccine come from an acting physician or Advance Practice Nurse for the purposes of Medical Assistance (MA) and MinnesotaCare reimbursement. In order to quickly comply with this emerging federal guidance, DHS enrolled pharmacies as providers. According to department data, there are currently 798 pharmacies that are billing for COVID vaccines. In order to comply with extending this practice permanently, DHS assumes that pharmacists would need to be enrolled as individual providers, rather than at the pharmacy level. According to department data, there are currently 798 pharmacies that are billing for COVID vaccines. It is estimated that an additional 500 individual pharmacists will enroll annually under this language. One FTE (MAPE 5L) is needed in the Medicaid Payments and Provider Services division to screen and enroll new individual pharmacists that will need to be identified on claims when billing for these services. This FTE will be working in MMIS, and state share is assumed at 29%. The FTE is assumed to begin October of 2022, and require an up-front administrative cost of \$15,150, and ongoing monthly administrative costs of \$1,275. Fringe benefits are estimated at 30%.

# 2) Specialized training, education, or experience ("preparation") required to engage in the occupation

# a. What preparation is required to engage in the occupation? How have current practitioners acquired that preparation?

Pharmacists are the foremost medication experts in the healthcare field. Except for pharmacists who graduated prior to 1990, all licensed pharmacists in Minnesota have an undergraduate degree and 4-year pos-doctorate education with 2 years of residency. As pharmacists advise patients for other medications, assessment of vaccine indication, effectiveness, safety, and convenience would be assessed before any administration allowed under the proposed legislation. Pharmacists are already educated on the recognition of adverse effects and allergic

reactions and are trained on how to effectively monitor and respond to allergic reactions. Pharmacists and interns are trained to administer vaccinations and perform basic life support through training programs accredited by the Accreditation Council for Pharmacy Education and the American Heart Association. Additional guidelines and training provisions are called out and specified in the legislation that would be followed by pharmacists, pharmacy interns, and pharmacy technicians. Training may occur as continuing education and organized into a protocol.

The bill language will require pharmacists, pharmacist interns and pharmacy technicians to have specific immunization and CLIA waived test training:

- "...the pharmacist, pharmacy technician or intern has successfully completed a program approved by the
  Accreditation Council for Pharmacy Education specifically for the administration of immunizations or a program
  approved by the board.
- The pharmacist, pharmacy technician or intern, utilizes the Minnesota Immunization Information Connection to assess the immunization status of individuals prior to the administration of vaccines, except when administering influenza and COVID-19 vaccines to individuals age three nine and older;
- Ghe pharmacist reports the administration of the immunization to the Minnesota Immunization Information Connection;
- The pharmacist, pharmacy technician or intern must, if the patient is 18 years of age or younger, inform the
  patient and the adult caregiver accompanying the patient of the importance of a well-child visit with a
  pediatrician or other licensed primary-care provider; and
- In addition, a pharmacy technician may administer vaccinations under this section while being supervised by a licensed pharmacist.
- The pharmacist is readily and immediately available to the immunizing pharmacy technicians;
- The pharmacy technician or pharmacy intern has a current certificate in basic cardiopulmonary resuscitation;
- The pharmacy technician has completed a minimum of two hours of ACPE-approved, immunizationrelated - continuing pharmacy education as part of their 2 year CE schedule;"
- b. Would the proposed scope change or reduction in regulation change the way practitioners become prepared? If so, why and how? Include any change in the cost of entry to the occupation. Who would bear the increase or benefit from reduction in cost of entry? Are current practitioners required to provide evidence of preparation or pass an examination? How, if at all, would this change under the proposal?

Pharmacists will continue to undergo the same basic training to be a licensed pharmacist in Minnesota (pharmacists in Minnesota have earned a Bachelor's of Science in Pharmacy or earn a Doctorate of Pharmacy from an accredited school of pharmacy and pass the National Pharmacy Licensing Examination). If a pharmacist, pharmacist intern or pharmacy technician wishes to provide the proposed patient immunizations and testing service, they would all be required to undergo a ACPE or Board of Pharmacy approved training program that educates about protocols for administering and monitoring vaccinations. Pharmacy technicians would be required to complete a certain number of hours of both training and a minimum number of hours on the job as a pharmacy technician. Pharmacists and pharmacist interns also undergo specific CLIA waived test administration and patient counseling education during their 4-year degree and 2-year residency. The pharmacists or their employers would be responsible for the cost of this training program, should a cost be associated with the training. There are also student loan forgiveness programs for debt reduction associated with the PharmD education.

c. Is there an existing model of this change being implemented in another state? Please list state, originating bill and year of passage?

For a deeper understanding of state pharmacy immunization and vaccination laws and policies please see the National Alliance of State Pharmacy Associations (NASPA's website: <a href="https://naspa.us/resource/pharmacist-authority-to-immunize/">https://naspa.us/resource/pharmacist-authority-to-immunize/</a>

Every state allows pharmacists and supervised pharmacy technicians to administer immunizations in some way and currently under the federal PREP Act declarations are allowed to provide all services included in this legislation, but laws vary widely in the details surrounding that authorization. The federal government has current guidelines from U.S. HHS that allows pharmacy technicians and interns to give COVID-19 and other vaccinations and tests under the supervision of a pharmacist when training has been completed. This proposal would allow the continuation of these services in Minnesota. (See the above training requirements and attached guidelines.)

## 3) Supervision of practitioners

a. How are practitioners of the occupation currently supervised, including any supervision within a regulated institution or by a regulated health professional? How would the proposal change the provision of supervision?

The Minnesota Board of Pharmacy regulates the pharmacist profession of pharmacy and grants licenses to pharmacists in Minnesota. The MBOP also registers pharmacist interns in Minnesota. Pharmacy technicians are also regulated by the MBOP. The MN Department of Health runs the Child Immunizations program in Minnesota as well as the MIIC reporting system that pharmacists utilize to comply with State requirements. The Minnesota Department of Human Services through their Medical Assistance (Medicaid) program and other health benefits they provide could be positively impacted by the proposed changes. The MBOP in conjunction sets Minnesota immunization policy for patients and providers such as pharmacists.

Pharmacists do not require direct supervision by another health professional in typical activity and would not need additional supervision to provide immunizations. Pharmacy technicians would be supervised by a licensed pharmacist. There is currently a 4 to 1 ratio of pharmacy technicians to a supervising pharmacist allowed under Minnesota law. This change would not affect the current supervision requirements or ratio. Pharmacists who currently operate under a collaborative practice agreement and exercise their professional judgement when advising patients regarding test results and medication management would continue to do work under the supervision of another health provider as well as any pharmacy technicians under the pharmacist's supervision.

In the fiscal note that addressed this exact bill language in 2022, the MBOP stated:

"Except for allowing technicians working under the direct supervision of a pharmacist to perform tests, the language related to testing doesn't actually change what pharmacists will be able to do. The current language allows pharmacists to perform tests and the Board has interpreted this to mean that they can effectively order the tests, collect specimens, notify patients of results, etc. The Board has also interpreted current rules and statutes to allow pharmacist interns, working under the supervision of a licensed pharmacist, to perform CLIA waived tests and administer vaccines. (As long as they have appropriate training).

Current state law does not allow pharmacy technicians to perform tests or administer vaccines. However, a federal declaration made under the Public Readiness and Emergency Preparedness Act has allowed pharmacy technicians to engage in these activities (the PREP Act declarations and its amendments pre-empt state law). So, technicians have been performing tests and administering vaccinations for almost two [now 3] years..."

b. If regulatory entity currently has authority over the occupation, what is the scope of authority of the entity? (For example, does it have authority to develop rules, determine standards for education and training, assess practitioners' competence levels?) How does the proposal change the duties or scope of authority of the regulatory entity? Has the proposal been discussed with the current regulatory authority? If so, please list participants and date.

The Minnesota Board of Pharmacy is the regulatory entity that oversees and regulates safety. The MBOP regulates all

practice and public safety aspects of the pharmacy practice for pharmacists, pharmacy technicians, and pharmacy interns given to it under MN statute Chapter <a href="Chapter 151">Chapter 151</a>. The Board develops rules, sets baseline training and educational requirements for becoming licensed in the state, ensures licensees meet continuing education requirements to maintain their license, and ensures compliance with the rules and laws governing pharmacy practice in Minnesota.

c. Do provisions exist to ensure that practitioners maintain competency? Under the proposal, how would competency be ensured?

The proposed changes require pharmacists, pharmacist interns and pharmacy technicians to complete a robust ACPE or MBOP approved immunizations training program. They also have to be certified in CPR and able to use a defibulator as well as work with patients who may have an adverse reaction. Pharmacists are required to take continuous training education on a 2-year schedule. (See the previous listed training and certification requirements.)

Here is an example of one of the immunization/vaccine administration courses offered at the University of Minnesota's College of Pharmacy:

"Immunization Delivery for Pharmacists consists of 20 hours including online self-study and participant live demonstration. Participants will be required to pass (70% or better) two quizzes: one mid-way through the course and a second quiz at the end of the online portion of the course.

Participants are required to pass both quizzes prior to attending the live portion of this activity. Information about live demonstration sessions will be communicated in the course Canvas site. "

- 4) <u>Level of regulation</u> (See Mn Stat 214.001, subd. 2, declaring that "no regulations shall be imposed upon any occupation unless required for the safety and wellbeing of the citizens of the state." The harm must be "recognizable, and not remote." Ibid.)
  - a. Describe how the safety and wellbeing of Minnesotans can be protected under the expanded scope or reduction in regulation.

The proposed changes will increase the safety of Minnesotans by decreasing the spread of preventable diseases. The proposal may also increase overall vaccine adoption by Minnesota patients because they can access their immunizations through a trusted health professional that is convenient to access in their local communities around the state. Patients will also benefit from reduced flu, Measles, COVID-19 and other diseases. They may be able to access treatment more quickly for ailments such as strep throat and the flu if they receive the relevant testing at the pharmacy. Pharmacy plays a vital role with medication education, management, administration and counseling. They are the most accessible trained health professional that Minnesotans will seek services and information about their health from this year. If Minnesota pharmacies can not utilize pharmacy technicians to help with patient immunizations, access to vaccines in the state will suffer because pharmacies will not be able to be adequately staffed to serve their patient populations.

b. Can existing civil or criminal laws or procedures be used to prevent or remedy any harm to the public?

Yes, see the MBOP's authorizing and penalties provisions in MN Chapter 151.

- 5) Implications for Health Care Access, Cost, Quality, and Transformation
  - a. Describe how the proposal will affect the availability, accessibility, cost, delivery, and quality of health care,

# including the impact on unmet health care needs and underserved populations. How does the proposal contribute to meeting these needs?

his proposal will increase the accessibility of vaccinations and CLIA-waived tests by allowing patients to receive them at their local pharmacy, which then increases availability and decreases cost. Pharmacists are the most accessible health professionals in Minnesota and are located throughout the state, often within 5 minutes or five miles of a patient. Pharmacists usually do not require appointments to have patient services provided. Often pharmacists are more accessible than primary care providers, who can have wait times of months and may be less convenient to see. A pharmacy visit does not charge a patient for an office visit or markup medication ingredient costs. Underserved and/or rural populations often present with barriers to clinic access, which is currently where patients would need to go to receive these vaccination and testing services currently not allowed for by current state statute. This proposal will enable Minnesotans to continue to access preventative care, inoculations and tests in a timely fashion, while also ensuring that a patient's health insurance will cover the vaccinations.

# From the Global Healthy Living Foundation report published January 2023

Pharmacists and their teammates contributed the pandemic recovery efforts with ">350 million clinical interventions to >150 million people in the form of testing, parenteral antibodies, vaccinations, antiviral therapies, and inpatient care." 6 A recent study

noted that there were 15.1% more pharmacy locations within low-income communities than the availability of physician practices. Several studies have also found higher vaccination rates in states that offer pharmacists full vaccination authority. The impact of pharmacists on immunization can also be seen in other countries. Higher immunization rates were reported in countries that authorized pharmacists to administer vaccines, such as United States, Canada, United Kingdom, Ireland, and Portugal, compared with those that did not provide such authorization.

#### Analysis of vaccine administration trends

- + Overall, across all vaccines for adults in-scope, a large majority of the administration took place at the pharmacy level compared to medical offices. As a result, 2020 and 2021 saw a steep increase in vaccine administration at pharmacies due to the COVID-19 vaccine.
- + The shingles vaccine also saw a similar trend, with a large majority of administration taking place at the pharmacy level across all of the years analyzed.
- + Pharmacies serve as an important part of the overall flu vaccination process. Notably, 60–70% of vaccination during flu season (third and fourth quarters) takes place at pharmacies. The trends in flu vaccine administration at pharmacies also indicate a 30–40% increase in claims for flu vaccines between 2018/19 and 2020.
- + A large proportion of pneumococcal vaccine administration also took place at pharmacies and the proportion. In the third and fourth quarters of any given year, around 40–50% of the administration occurs in a pharmacy setting. The overall number of claims also consistently increases in these quarters compared to the first and second quarters.
- + These vaccine administration trends generally hold irrespective of gender, race and income. For some vaccines, Hispanic and Asian American populations see a larger proportion of administration at pharmacies compared to other racial/ethnic categories. Proprietary IQVIA data has been utilized to understand the location of administration of several adult and children's vaccines (Methodology in Appendix).

Assessing the administration of adult vaccines showcases that pharmacies are a crucial node in the overall vaccination efforts.

#### **ADULT VACCINES**

Overall, across all vaccines for adults in-scope, a large majority of the administration took place at the pharmacy level. 2020 and 2021 saw a steep increase in vaccine administration at pharmacies due to the COVID-19 vaccine (Exhibit 1). For COVID-19, a substantial amount of vaccine administration has been taking place through multiple channels (pharmacy, doctor's office, federal and state government vaccination sites). For federal and state government vaccination sites, vaccines may have been shipped directly to the site, therefore a claim may not be

generated. The data captured by the IQVIA databases covers only vaccinations that had a claim associated with it, this is approximately 50% of the total doses administered second half of 2021 onward for COVID-19 vaccines (please see appendix for more details).

The analysis shown below only represents the cases where a claim was available for all vaccines. Temporary and government public health sites where a claim was not generated are excluded from this analysis. Excluding temporary and government public health sites, more than 90% of COVID-19 vaccinations provided through either medical centers or pharmacies were delivered at pharmacies in both 2021 and 2022. This trend holds if the data is analyzed by race, gender, and income levels (Exhibit 2).

The trends in location of adult vaccine administration discussed above did not vary substantially based on gender, and household income. However, there are variations in the location of vaccine administration if the data is analyzed at a race and ethnicity level. Hispanic and Asian populations receive a larger share of vaccines at pharmacies compared to other race/ethnicity categories. For example, in the case of pneumococcal, black and white populations received around 30–40% of their vaccination at pharmacies, while Hispanic and Asian patients received approximately 45–55% at pharmacies (Exhibit 7). A similar trend can also be seen in the case of other vaccines for adults. While across all vaccines in 2021 and 2022, there is no substantial difference in vaccine administration location at a rural vs. urban level, differences in share of administration at pharmacies can be seen for some vaccines at rural vs. urban level, with rural areas seeing a higher proportion of pharmacy administration (Appendix)...

#### **CHILDREN'S VACCINES**

Similar to the trend in adults, excluding temporary and government public health sites, a large majority of COVID-19 vaccines were administered at the pharmacy level compared to a non-pharmacy medical setting (Exhibit 8). One of the key aspects of the PREP act has been that it has allowed pharmacists and pharmacy technicians (under supervision by a qualified pharmacist) nationwide to administer COVID-19 (3+), pediatric (3–18) and flu vaccines (18+), without a prescriber order. The PREP Act preempts state laws that would prevent providers from acting in accordance with HHS's declarations regarding vaccination, and 46 states (88%) have accepted this preemption.11 Currently, 25 states have given permanent vaccination authority to pharmacy technicians while others do not provide permanent authority but may allow authority for certain vaccines under specific conditions.11 As pharmacies have played a crucial role in the administration of COVID-19 and flu vaccines during the pandemic, it is worth assessing the role of pharmacy technicians to understand the importance of providing permanent authority to them. With multiple adult vaccines currently in development and the expected need for further COVID-19 boosters, pharmacists are likely to continue being an essential part of the immunization process. As the public health emergency concludes and we enter the post-pandemic phase, lessons learnt from the pandemic must be incorporated into future policies to ensure that equitable access to vaccines continues to be provided.

b. Describe the expected impact of the proposal on the supply of practitioners and on the cost of services or goods provided by the occupation. If possible, include the geographic availability of proposed providers/services. Cite any sources used.

As previously mentioned, the pharmacist is the most accessible and trained health professional able to provide this service for patients. Authorizing pharmacists, pharmacist interns, and pharmacy technicians in Minnesota would have no negative impact on the number of pharmacists in Minnesota. It will also not impact any other health provider profession, other than to alleviate overburdened hospitals, clinics and provider offices, that currently has the ability to prescribe and work with patients using these medications. However, if Minnesota pharmacies can no longer allow their pharmacy technicians to inoculate patients, Minnesota pharmacies could become overwhelmed with patient vaccination administration requests. Not having pharmacy technicians vaccinating patients also will have a severe impact on workforce shortages in many pharmacies around Minnesota.

c. Does the proposal change how and by whom the services are compensated? What costs and what savings

#### would accrue to patients, insurers, providers, and employers?

The proposed legislation/change does not require or mention anything about reimbursement. Both private and public payer reimbursement would not be impacted by this legislation. Overall, providing patient immunizations should reduce healthcare costs for Minnesotans.

d. Describe any impact of the proposal on an evolving health care delivery and payment system (eg collaborative practice, innovations in technology, ensuring cultural competency, value based payments)?

Not applicable. [See earlier mentions of collaborative practice agreements and protocols.]

e. What is the expected regulatory cost or savings to state government? How are these amounts accounted for under the proposal? Is there an up-to-date fiscal note for the proposal?

Please see the discussion points regarding costs and savings noted in the above (1, "Fiscal Impact") paragraphs. Please also see the Senate Fiscal note for SF3940 from the 2021-22 legislative session.

# 6) Evaluation/Reports

Describe any plans to evaluate and report on the impact of the proposal if it becomes law, including focus and timeline. List the evaluating agency and frequency of reviews.

There are no plans to evaluate and report on the impact of the proposal if it becomes law at this time. However, there are both institutional and private organizations that are or have studied the impacts vaccine immunization and point-of-care testing being administered in a Minnesota pharmacy setting.

### 7) Support for and opposition to the proposal

a. What organizations are sponsoring the proposal? How many members do these organizations represent in Minnesota?

Please see the above pharmacy supporting organizations and member information in our answer to question 1-b above. In addition to those organizations, the MN Retailers, the MN APRNs, the MN NNPs and MN Grocers support this legislation as well as other patient member organizations.

b. List organizations, including professional, regulatory boards, consumer advocacy groups, and others, who support the proposal.

Minnesota Pharmacists Association
Minnesota Society of Health-System Pharmacists The
University of Minnesota College of Pharmacy
The Minnesota Retailers Association
The Minnesota APRNs
The Minnesota NNPs
The Minnesota Grocers Association

We also sought technical assistance from the MBOP, MDH and DHS.

c. List any organizations, including professional, regulatory boards, consumer advocacy groups, and others, who have indicated concerns/opposition to the proposal or who are likely to have concerns/opposition. Explain the concerns/opposition of each, as the sponsor understands it.

We do not know of any organizations who actively oppose this legislation. We have and are working with each of the above-mentioned organizations as well as the Minnesota Medical Association to gain consensus for state codification of

current federal PREP Act authorities that will go away May 11<sup>th</sup>, 2023.

d. What actions has the sponsor taken to minimize or resolve disagreement with those opposing or likely to oppose the proposal?

Not applicable.